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MANUFACTURE OF BONE FRACTURE STABILIZING PLATES IN BIOCOMPOSITE BY RESIN INFUSION AND HAND LAYUP: A COMPARISON

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Abstract. *Bone fractures can occur by accident, shaving, or advancing age at any time in a human's life. To solve this fracture problem, fracture stabilizing plates are used in the bone healing process after the fracture has occurred. These plates are screwed to the intact parts of the fractured bone, keeping them together, enabling the recovery of integrity by means of bone neoformation, forming bone callus in the fractured region. This type of implant is mostly manufactured in metallic materials. However, these materials have some disadvantages, such as fatigue failures, allergic reactions, high cost, reduction in bone density due to the high stiffness of the implant, etc. An alternative are fracture-stabilizing plates made of composite material that, besides having a lower cost, also present a greater mechanical compatibility with bones. Thus, the aim of this work is to manufacture and characterize Dynamic Compression Plates (DCP) in polymeric composite material, made of polyurethane (PU) derived from vegetable oils and reinforced with fiberglass, aiming at a process that guarantees an adequate manufacturing for the safe use in medical implants. To this end, fracture stabilizer plates were fabricated in a metallic mold and also by the Hand Lay Up method. The present work is important because it provides an alternative to the metals used, as well as because it is a non-heat conducting material, which is one of the problems with stabilizer plates in metals. The composite plate will have the versatility of the orthopedic surgeon to choose where he will make the holes for fixation of the plate, another advantage is that one can project the desired properties in the plate, i.e., properties such as strength and stiffness not so above the bone, so that the body allows bone neoformation in the fractured region.The mold manufactured reached the expected result since it allowed to manufacture fracture stabilizing plates in scale-like to the base with low variation in thickness. On the other hand, the plate manufactured by the Hand Lay Up method had a variability in thickness, but a significantly lower presence of trapping air was noted compared to the first method, which results in a more uniform and resistant material.*
Keywords: *bone fracture stabilizing plates, composite manufacturing, biocomposites …*

1. INTRODUCTION

According to Cunha (2021) bone fracture is a break or rupture in the bone that can be caused by traumatic incidents such as falls, accidents, and/or for pathological reasons where the bones are weakened due to health conditions such as osteoporosis or bone cancer/tumors

In the paper of Hernigou (2016) shows that the first surgical techniques for treating fractures with plates were developed in the early 19th century. The aim of this treatment is to achieve optimal fixation of the fracture, allowing its mobilization and promoting successful bone restoration.

Recently, (Zhang et al., 2022) showed that the use of plates and screws to stabilize the fracture is intended to ensure healing, and these plates may be made of biocompatible material or not.

The process of restoration after a fracture, also called bone healing, is a complex physiological process involving several events, including cellular and biomechanical factors. According to (LI, et al., 2019) , approximately 5% to 10% of bone fractures do not heal normally and therefore delayed healing or poor fracture union is quite common.

Thus, micro-movement is desirable in fracture healing, as it ensures alignment and stability of the fractured region. High stiffness impedes this micro-movement and can increase the time of bone callus formation and delay recovery. (Tong, 2007).

Thus, fracture stabilizing plates must have adequate stiffness and modulus of elasticity to be used in medical applications.

However, in the paper of (Mehboob and Chang, 2014) explains that the material used for their manufacture is usually metallic, which has some disadvantages such as corrosion, fatigue failure, allergic reactions and losses in the accuracy of radiographs In addition, according to (LI, et al., 2019) the Young's modulus of metallic materials is approximately 5 to 10 times that of human bone (or bone tissue).

Thus, the use of composite materials to replace metallic ones for the manufacture of these implants has been an alternative to overcome such problems. However, when working with this type of material, large-scale repeatability is difficult to achieve, in addition to the processes not having a high standardization and often requiring specific machines according to the paper of (Advani ,2012). Also, recently work (Chohan et al., 2020) shows there is a very high number of combinations for the composite material and fiber configurations, which makes characterization and numerical analysis difficult compared to isotropic materials

These composite materials are able to provide mechanical properties that are not found in conventional polymers or metals, and thus, it is possible that the stiffness of a fracture stabilizer plate manufactured in composite material is closer to the stiffness of human bone, preserving important mechanical characteristics such as tensile strength and modulus of elasticity (Retwisch, 2009).

Therefore, the objective of the present work is to manufacture and characterize fracture stabilizer plates in polymeric composite material made of polyurethane and reinforced with glass fiber and to develop a manufacturing process by resin infusion and by hand layup to compare the results.

2. METODOLOGY

In the present work, two fracture stabilizing plates models were developed, using two production methods: with a previously machined metalic mold and through the lamination method. Prostheses were produced and several implants were tested in polyurethane resin supplied by the Kehl company, with two reagents: AG201 (isocyanate) and AG202 (polyol) reinforced with glass fiber.

The material chosen for the metalic mold was SAE 1020 steel, for its machinability, mechanical strength and because the machining center used to build it had tools suitable for it. For the core of the mold, PVC was chosen, as it is a material of good machinability and has a good surface finish, in addition to having low adhesion to the resin, preventing it from sticking and making it difficult to demold the plate.

The specimens for tensile testing were manufactured by the lamination method to ensure the same mass fraction as the laminated plates.

In the lamination method, the Hand Layup method was used for the production of the plates. To reproduce the radius of the fracture stabilizer plate, the laminated plates were milled, and to give the final shape, the milled plates were cut on a multifunction machine.

2.1 DCP Plate.

The fracture stabilizing plate that will be moulded is a base plate for the manufacture of DCP plates of the model presented by figure 14. It is composed of titanium and is present in the Composite Materials Laboratory of UTFPR/CP. It was decided to manufacture without holes so that the surgeon can decide where to drill according to the desired application.

Figure 1 – DCP Plate

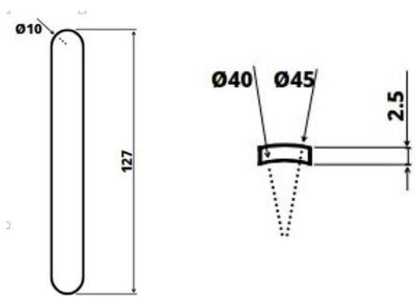
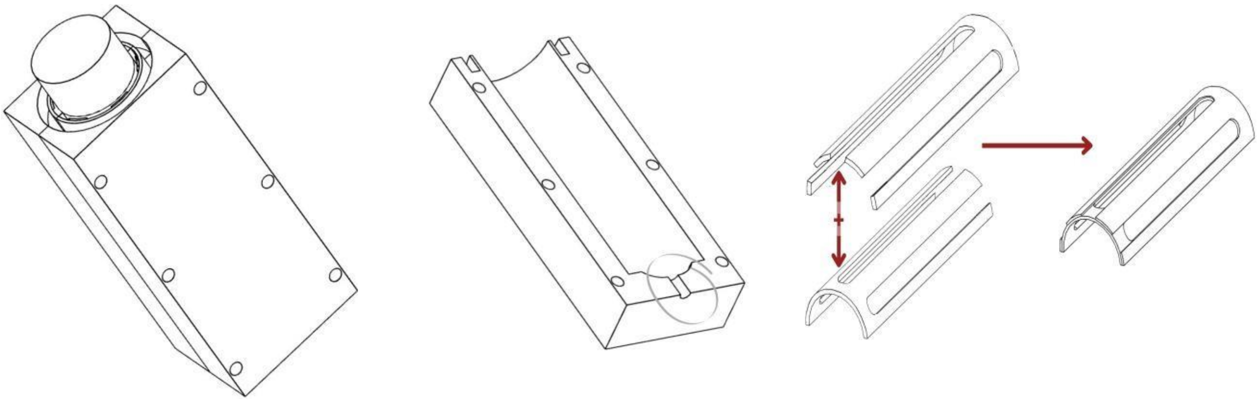


Figure 2 – Plate dimensions

The model was designed using Solidworks software and its dimensions are shown in Figure 2, presented below.

2.2 Metalic mold

In the resin infusion method, was utilized the metallic mold proposed by Durigan (2022). The mold is divided into parts, being the outer mold, inner mold, core and suction dome. The assembly of these first three is given by Figure 3, below. Figure 3a shows the assembly of the mold with the absence of one of the parts of the outer mold, for better visualization. Then, the Figure 3b shows the external mold e 3c the core.



a) b) c)

Figure 3 – Metallic mold

2.3 Manufacturing of stabilizing fracture plates

2.3.1 Resin Infusion

The first test of the manufactured mould took place in the following configuration: a layer of fiberglass fabric was positioned between the two parts of each of the cores, so as to be centered on each of the plates. Before assembly, the entire interior of the mold was covered with a thin layer of wax, in order to prevent the resin from detaching from the mold, since the cores were machined in PVC, which can adhere to the resin and be damaged by the removal of the mold parts. A surgical hose was positioned with its tip in the entrance cavity before closing the mold, a 60ml syringe with the PU and calcium carbonate mixture is fixed in it and at the other end the tank that connects the system to the vacuum pump is fitted. The assembly is shown in figure 4 below.

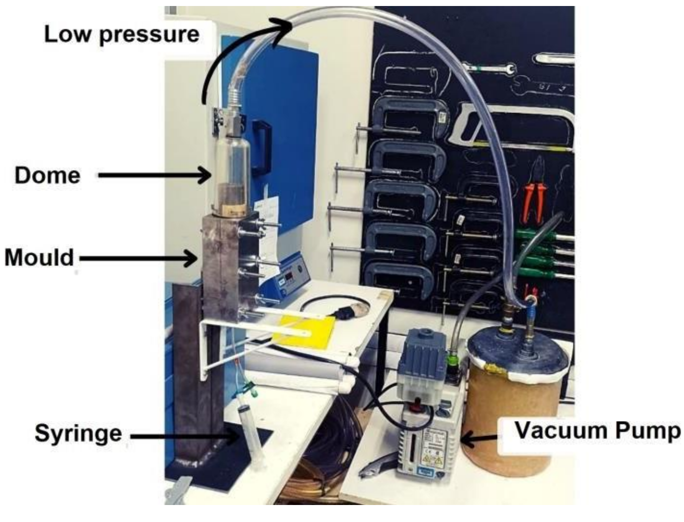


Figure 4 – Test 1 configuration

In the second test was decided not to use the vacuum pump to feed the system. Instead, force was applied to the syringe nozzle manually to feed the mold. The ratio of polyol and isocyanate was maintained from the previous experiment, being one to one, resulting in 60 grams of the polyurethane mixture. The mixture, already homogenized, was placed in a vacuum dome, shown by figure 3, and the pressure was removed and added twice at one-minute intervals.

Figure 5 – Vacuum dome

After this process, the mixture was placed in the mold and brought to the pressure vessel with 4 bar of inner pressure as shown figure. The mixture remained for 40 hours in the vessel, with the purpose of guarantee the curing of the mixture.

Figure 6 – Pressure vessel

2.3.2 Hand Layup

In the Hand Layup method, no investment in equipment is required to manufacture the composite. In this process, the reinforcement is placed in a mould layer by layer, which can be in the form of bidirectional mats and/or fabrics. The resin is impregnated into each overlapping reinforcement layer. In these composites, volume fractions of voids of about 15% are observed according to (Neto, structural composites, 2008). Curing is carried out at room temperature or in an oven, depending on the type of resin or specific post-curing requirement.

In addition to the injection mold it was decided to manufacture a flexible mold using flat bars, so that the plates were manufactured by the lamination method. The flat bars serve to delimit the resin filling space and have a height of 3.17mm. Figure 5 shows the assembled mold ready for lamination. According to (Adenyi, 2021) the Hand layup method is used for metal reinforced composites but is also widely used for fibre reinforced composites and this method is popular due to the low cost and does not require the availability of electricity and its operation cost. It is equally effective especially in laboratory experiments where small quantities of raw material is involved.

Figure 7 – Flexible mold

For the manufacture of the fracture stabilizer plates by the hand layup method, the following steps were adopted:
1 - Assembly of the flexible mold using the stainless steel flat bars, gluing them on a table to delimit the resin filling space.
2 - Addition and spreading of wax on the table to facilitate the subsequent demolding of the polyurethane resin.
3 - Cutting the fiberglass fabric, cutting them into several rectangular pieces, being in all 10 layers of fiberglass fabric.
4 - Pouring and spreading the resin in the flexible mold with the aid of a trowell.
5 - Place the assembly in the pressure case and let it cure for approximately 24 hours.
6 - Demolding of the entire polyurethane plate
7 - Cutting of 7 fracture stabilizer plates, the same being cut out of the whole plate.
8 - Finishing to give the final shape to the fracture stabilizer plates.

The Figure 6 shows some highlighted steps, being a) assembly of the flexible mold, b) cutting of the fribra fabrics, c) binding of the resin in the fiberglass and d) assembly placed in the pressure vessel.

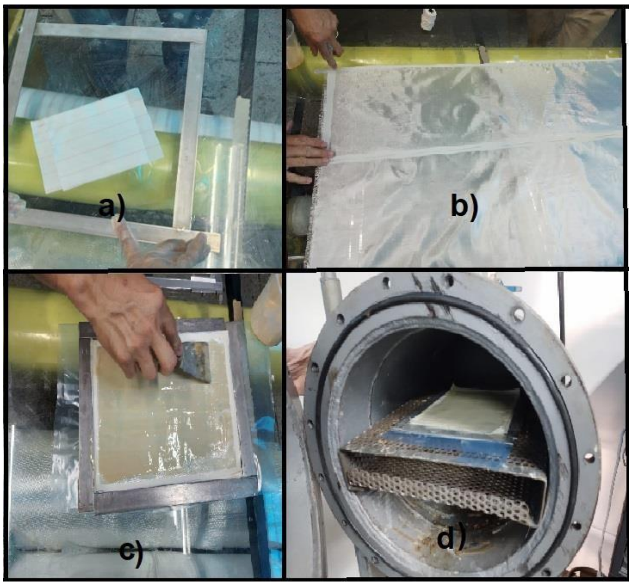


Figure 8 – Hand Layup Process

2.3 Tensile Test

The tensile tests were conducted on a universal testing machine at the Testing Laboratory of UTFPR.

Following ASTM D638, the displacement speed was constant and equal to 5mm/min and the distance between grips 115mm. A preload of 1N was applied.

The acquisition system of the testing machine allowed to obtain the displacement of the grips and the applied force. With this information, the engineering stresses can be calculated and the actual stresses can be estimated.
In order to capture images to apply the digital image correlation (DIC) method, a Canon® EOS 7D camera was used and synchronized with a computer by the EOS Utility® software. Additionally, a lighting system was set up and image capture was performed every 5 seconds. To use the CDI method, it was necessary to paint the specimens, as shown in Figure 7, and the photos obtained were processed in the Gom®Correlate 2019 student license software.

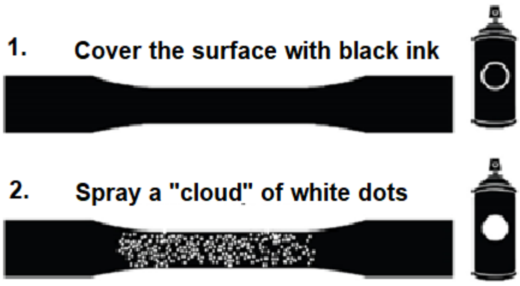


Figure 9 – Painted specimens

After the painting process the specimens were as shown in the figure 8 . The experimental apparatus set up for the tensile test is shown in figure 9.

a) b)

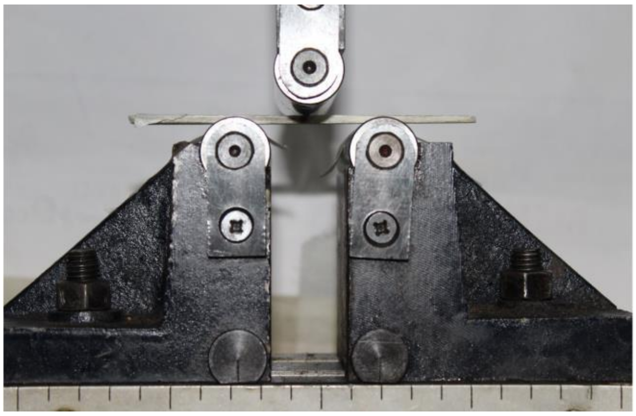
Figure 10 – a) Painted specimen e b) lightining system to digital image correlation

Bending Test

The bending tests were performed using the universal testing machine, Shimadzu Autograph AGS-X 10KN, at the Testing Laboratory of UTFPR.

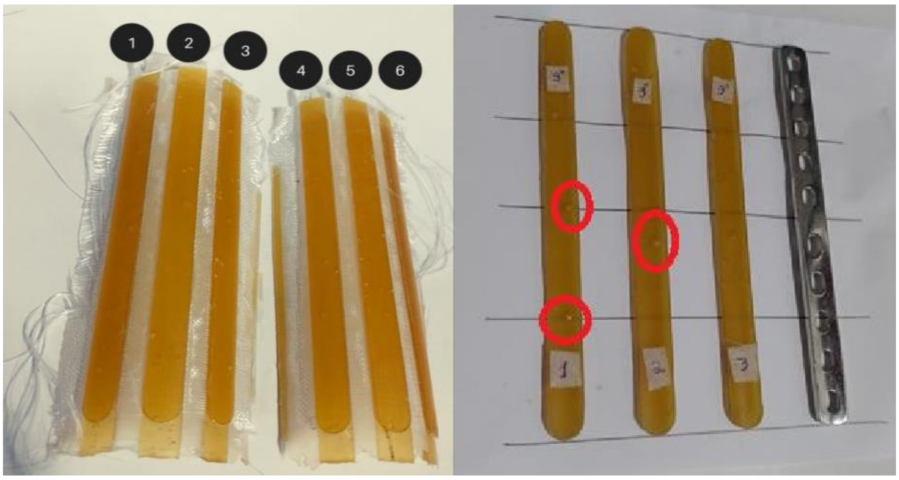
The ASTM D790 standard describes, as well as the ISO 178 standard, the 3-point bending tests on rigid and semi-rigid plastics as well as on fibre composites with long fibre reinforcements.

The test is in accordance with ASTM D790-03 (4), where the specimen is positioned so that the load is applied in the centre of the specimen at a speed of 2 mm/min. The experimental apparatus is shown in figure 11.



Results

In the second test by resin infusion, the plates met the desired dimensions and geometries, however some trapping air bubbles were noted along the plates, image 11a shows the result of the test and 11b shows the plates after finished, next to the titanium DCP plate that the work was based on.



a) b)

Figure 11 – DCP polyurethane plates (resin infusion method)

The manufacture by hand layup method fabricated the stabilizing fracture plate as shown in Figure 10. In this test it was possible to see that the manufactured plate is very similar to the base plate, and no surface bubbles were observed in the final product. However, some plates showed low thickness after finalization, which can be explained by the thickness variation along the manually laminated plate. The dimensions ate shown in the table 1.

Bone fracture plate	**l (mm)**	**e (mm)**	**c (mm)**
P1	10,20	2,50	126
P2	10,40	2,30	127
P3	10,40	2,30	127
P4	9,70	2,70	127
P5	9,20	2,70	118
P6	9,00	2,20	126

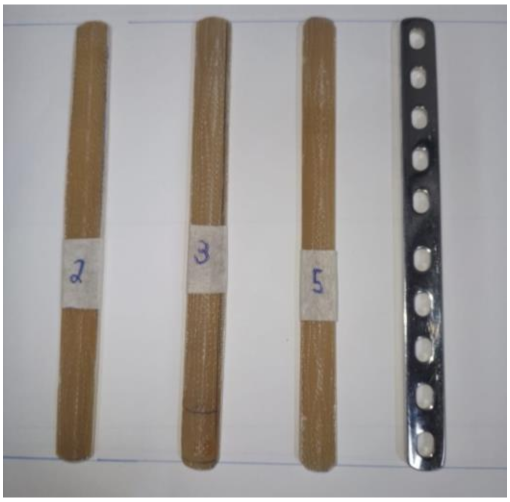


Figure 12 – DCP Polyurethane plates (hand layup method)

After the tensile tests, the result found in the GOM correlate software was as shown in figure 11. The samples had a small variation in the deformation, being observed a maximum value of 2.5 % aproximately.

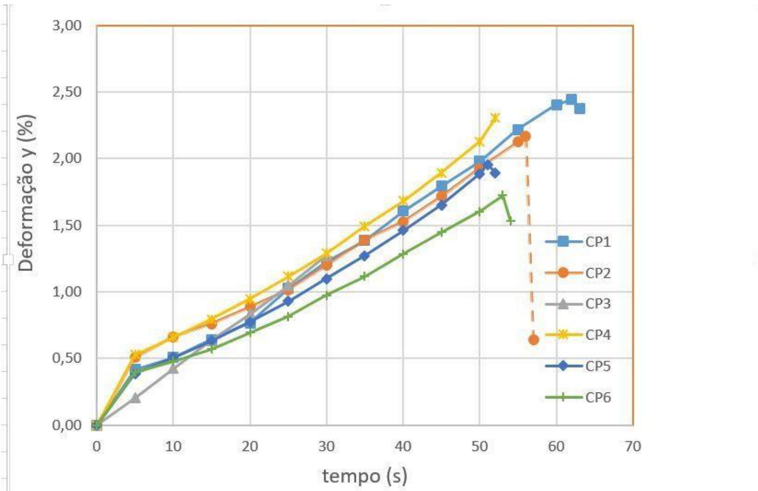


Figure 13 – Deformation (%) x time

With the results obtained by the universal testing machine it is possible to obtain a stress x strain curve, as shown in Figure 12. Approximately 300 MPA was found for the maximum stress.

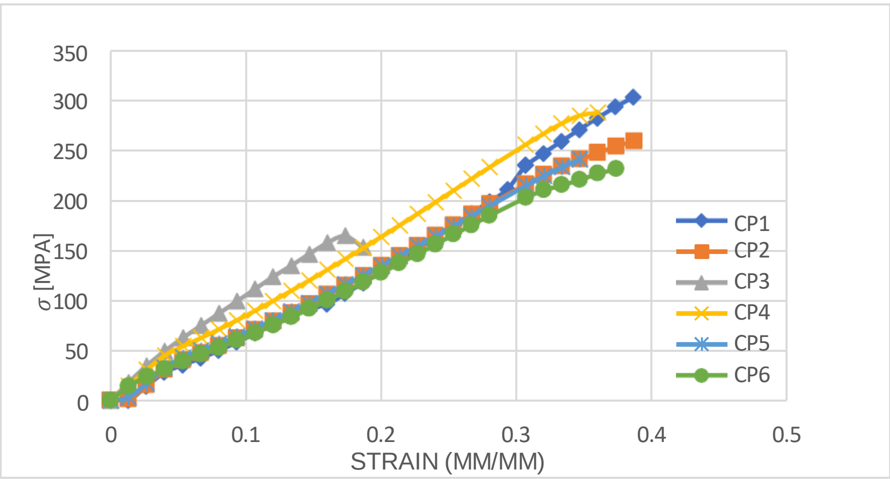
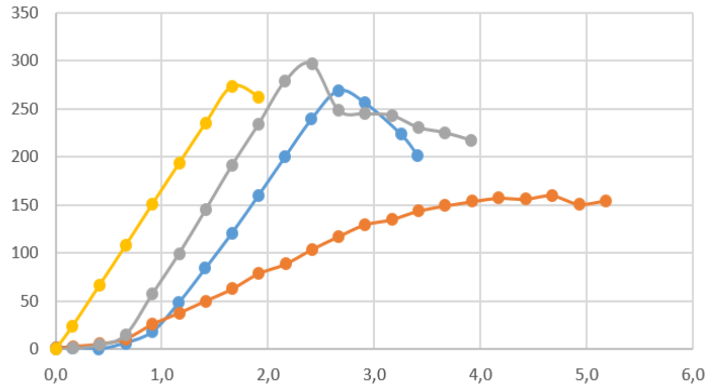


Figure 14 – Stress x strain curve

The results of the bending test are shown in Figure.The stress values achieved were higher than those found in the work of (Sales, 2020) where he carried out a 4-point test, while the deflection was lower than that observed in the same work, with a difference of around 10 mm.



3. CONCLUSION

In the Hand Layup method test it was possible to see that the manufactured plate is very similar to the base plate, and no surface bubbles were observed in the final product. However, some plates showed low thickness after finalization, which can be explained by the thickness variation along the manually laminated plate. In the second test by resin infusion, the plates met the desired dimensions and geometries, however some trapping air bubbles were noticed along the plates. It was possible to notice that each method has its advantage, the plates manufactured by resin infusion have the advantage of producing more uniform plates in dimension, since a mould is used for this purpose, on the other hand, the plates manufactured by the hand layup method have a greater variability in dimensions, but low presences of bubbles are noted, which makes the material with a good strenght.

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